MICROSTIMULATORS AND MICROTRANSDUCERS FOR FUNCTIONAL NEUROMUSCULAR STIMULATION

Contract #N01-NS-5-2325
Quarterly Progress Report #14
Period: June 10, 1998 – September 9, 1998

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12/27/98
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Abstract

We are developing a new class of implantable electronic devices for a wide range of neural prosthetic applications. Each implant consists of a microminiature capsule that can be injected into any desired location through a 12 gauge hypodermic needle. Multiple implants receive power and digitally-encoded command signals from an RF field established by a single external coil. The first two types of implant that we have made were single-channel microstimulators equipped with either a capacitor-electrode or an internal capacitor that stores charge electrolytically and releases it upon command as current-regulated stimulation pulses. We are also working on implants equipped with bidirectional telemetry that can be used to record sensory feedback or motor command signals and transmit them to the external control system.

Work at Queen's has concentrated on BION sealing hermeticity testing. A summary of the hermeticity requirements and strategies is provided. The high pressure bomb [finished devices soaked in saline with 160 atm He pressure head (2,240 psi)] has proven to be a simple and reliable way to reveal latent package faults at the end of production. All devices that have survived 24 hours in this bomb are still functioning in chronic tests that involve either additional high pressure bomb time or continuous output during elevated temperature cycling. Manufacturing yield on these devices was 92% with first generation tooling, which is now being further refined.

Work at the Foundation has concentrated on improving the reliability of the electronics module. The new chips have turned out to be very reliable and robust in detecting data, power conversion, and control.

Hermeticity Requirements and Strategies

Achieving and demonstrating functional hermeticity is a difficult problem in very small devices intended to have very long lives such as the BION. The basic considerations are summarized in Figure 1, which provides a nomogram for determining time (s) from volume (cc) divided by leak rate (cc/s), as shown by the three log scales in Figure 1. Each of these terms requires some consideration to determine its appropriate value:

VOLUME: The approximate total volume of various implantable electronic devices is shown by the position of the names above the volume scale at the top. The diagonal lines down and rightward indicate the correction to reflect the volume of water vapor that could be admitted to each package before reaching the dew point at body temperature (6% water vapor), assuming 50% free volume in the package.

Leak Rate: The leak rate depends on the pressure head, which is assumed to be 1 atm., and the size of the gas molecules. The leak rate of water vapor is about half that of helium, the gas usually used in leak detection equipment. The equivalent sensitivity ranges of various conventional and experimental testing methods are shown in the boxes immediately above the leak rate scale.

Life Time: Straight lines that pass through a particular volume and leak rate intersect the minimal life time expected of a device that has passed such a leak test at the limits of its sensitivity (equivalent values in calendar time and seconds shown above and below the log time scale, respectively).

The most sensitive conventional leak test is the determination of He by a mass spectrometer in the inlet of a high vacuum pump. One side of the seal to be tested is evacuated and He is sprayed over seals to be tested from the outside. The lowest leak rate that can be so detected with our Alcatel Helium Leak Tester is 2 x 10-11 cc/s, which appears as a small fluctuation in the background level (typically around 10-9 cc/s) with each squirt of helium. There is no upper limit to detectable leaks; gross leaks appear as a failure to reach the usual starting vacuum level. The nomogram indicates that a device leaking at just below the detectable limit (leftmost dashed line) could reach the dew point in a matter of days, assuming that all of the water vapor remained free to condense. In fact, at least some water vapor will be absorbed by the various materials within the package, effectively increasing the apparent volume of water vapor that the package can hold. This can be enormously increased by incorporating a small amount of a getter - a material that specifically absorbs water. The BION is designed to incorporate a slug of silicone with a getter, occupying about 10% of the volume of the package. This produces a very large increase in the apparent volume for water vapor (arrow marked 10% getter). In all of the devices built to date, this getter has been omitted to increase the sensitivity of accelerated life tests for any hermeticity problems.

The He sniffer test described above is applied routinely to all of the critical glass-to-metal and glass-to-glass seals at each stage of production, but it cannot be applied after the Ta tube is sealed (9). Fine leak detection of a completely closed capsule is usually done by incorporating helium into the sealed package or by forcing it in through any leaks using a high pressure bomb. The minimum helium leak rate that can be detected this way is limited by the background level of the leak detector (typically 10-9 cc/s). For a BION with a getter, this corresponds to 30 years of life (assuming the flaw does not deteriorate). The maximum detectable leak rate is limited by the tendency of any trapped helium to be pulled out of the package during the initial pumpdown, before it can be detected. This corresponds to about 10-6 cc/s for the very small BION. Gross leaks are usually identified in closed packages by conventional bubble testing, in which the completed device is immersed in heated Freon. The increased internal pressure results in visible streams of bubbles. Even with careful inspection, it is difficult to visualize bubbles at rates lower than 10-4 cc/s, resulting in a window of vulnerability (empty box in Figure 1).

We have pursued two strategies to close the window of vulnerability. The first was a bomb/bubble tester proposed by Chuck Byers for the A.E. Mann Foundation and described previously. It was designed to extend the sensitivity of bubble detection by providing microscopic inspection and trapping of bubbles during the process of gradually releasing a 10 atm bomb pressure under manual control. We have had to abandon this because of false positive results from helium gas trapped in pores of the Ta and Ir electrodes and in surface imperfections in the machined transparent enclosure.

The second strategy is a brute-force accelerated life-test in which we try to force water vapor into the package at very high pressure (typically 160 atm provided by the unregulated He tank). The amount of water that has to be forced in to condense to the point of being visible on the glass walls of the package or causing failure of the electronics depends on the apparent volume of the package, including any gettering action. If this test is applied simply to close the window of vulnerability between 10-4 and 10-6 cc/s, then even a package with 10% getter would require less than one day of high pressure bombing to fail. Slower leaks in the range 10-6 to 10-9 cc/s should all be detected by the trapped He detector.

In practice, we have found the high pressure bomb test to be even more effective than anticipated. That is because the only real defect likely to arise between the even more sensitive He sniffer test and the final sealing steps are occult cracks in the glass bead during the plasma needle welds described above. These cracks may not even be leaking if they are superficial, but they are likely to deteriorate in the presence of water. We have found empirically that immersing the BIONs in saline during bombing at 160 atm rapidly accelerates the propagation of microcracks, resulting in visible cracks with gross accumulation of water inside the glass package. We have generated such occult microcracks while experimenting with weld schedules and fixtures. However, no BION package that survived the first 24 h of high pressure bombing has since failed in either continuous high pressure bombing or continuous active temperature cycling in saline (see below). A 24 h high pressure bomb test is now a standard part of the final QC procedures on all manufactured BIONs.

Current Glass Package Processes

The revised assembly tree in Figure 2 summarizes the current fabrication steps and provides a numbered key for all critical joints and seals. Figure 3 provides a detail of the newly developed processes at the iridium electrode end of the package. This end is the most critical for manufacturing yields and it is also more difficult to test because it is sealed last. There have been almost no manufacturing, yield, or reliability problems involving the seals at the other end, which are also glass to glass and glass to tantalum. The previous quarterly progress report summarized the previous problems with glass seals to the tubular feedthrough and their successful resolution.

Figure 3 provides a schematic of the first generation production tooling used to produce seals 9 and 10 of the devices whose test results are described below. A pulse of energy is provided from the argon plasma needle jet (shown at right) to the grounded Ta clamp on the Ta tube. This is done under a curtain of the same inert gas mix that is used to backfill the device after vacuum bakeout (70%Ar-25%He-5%H). The arc melts the end of the tube into a ball (9), effectively completing the hermetic seal. The hot Ta stem just behind the molten Ta ball then melts the inside walls of the Ir washer, which is held in position by another Ta clamp. The pure Ta ball that seals the end of the tube is a smooth, specularly reflective hemisphere with no tendency to generate cracks, as was seen previously with YAG laser welds that produced alloying with Pt or Ir. The Ir electrode is tightly attached and has no changes to its tumbled surface texture. The fixturing results in a gap of 0.75mm between the Ir electrode and the end of the glass bead. This seems to be the smallest allowable distance so that the heat pulse dissipates sufficiently as it flows along the Ta tube (.020" o.d. x .012" i.d.) to the Ta clamp and heatsink so as to avoid cracking the glass bead previously sealed to it (5).

Manufacturing Yields and Accelerated Life-Test Results

The previous build (dated Aug. 18, 1998) using prototype tooling and processes still under development (described in our previous QPR) had a manufacturing yield of 20/28 through capsule closure (#8) and 14/20 through final seals (#9/10). The high pressure bomb test was not yet available and there were substantial problems with occult cracks in the completed units due to the primitive fixturing. Four devices sent to AEMF passed their high pressure bomb (24 h @

1600 psi) and bomb-bubble tests. Another eight working devices were started on chronic, active saline soak and temperature cycle testing (continuous maximal rated output, 3h @37(C & 9h @77(C). Four of these eventually failed from progression of occult cracks (at 7, 9, 10 and 13 days) while the other four are still functioning after 31 days.

The most recent build (dated Sept. 18, 1998) used the first generation tooling described above. Yield through all seals and helium leak testing was 100% (24/24). Four of these devices had special moisture-sensing circuit configurations and were sent to IIT for soaking and impedance spectroscopy testing for moisture. Thirteen were tested for 24h in the high pressure bomb (2600 psi), resulting in one crack after 24 h. This test is now a standard part of the manufacturing process, so the yield on manufactured devices after completion of all manufacturing and QC procedures is actually 92%. Six devices have been on long term testing in the high pressure bomb, still working after 27 days. Four were started on chronic, active soak and temperature cycling and are still working after 15 days as of this writing (Oct. 20).

We are now rebuilding some of the bearings and collets in the CO2 laser to improve alignment and package reproducibility. We are designing further improvements to the fixturing for the plasma needle welder to improve consistency, operator time and control of back-filled gas. In the next quarter, we will process at least one additional build using the present generation electronic subassemblies and then another build as soon as the next generation ASIC and ceramic (PCB have been built into new electronic subassemblies. Selected devices will be continued on long-term high pressure bomb and chronic active soak and temperature cycling to accumulate long-term data. We will build molds and produce getter slugs for the new electronic subassemblies, but we will not incorporate them until we are close to building and testing human-implantable units.

IMPROVED 2-MHZ MICROSTIMULATOR ASIC DEVELOPED AT AEMF

Dedicated Wafer Run

The recent chip fabrication for the Improved Microstimulators has been done using the MOSIS service. This keeps some costs low, but it has several disadvantages at the present stage of development: MOSIS per-chip costs are very high since the number of chips is very small. The MOSIS schedule does not always mesh well with our schedule. Perhaps most importantly, MOSIS can (economically) provide chips, not wafers.

The issue of wafer-versus-chip production is important at this stage because of the post-processing which we must now perform. To provide an easier fit in the small Microstimulator package, the chips must be lapped from a thickness of about 500 microns down to under 200 microns. While this can be done on individual chips, it is much easier (and more economical) to do it on an entire wafer before it is diced into individual chips. As mentioned in the previous report, an additional passivation layer (probably silicon nitride) is needed to protect the chips from damage due to the attached ferrites. This passivation layer must then have holes etched to provide access to the metal pads on the chips; processing of this type can only be economically done photo-lithographically on a wafer scale.

We have scheduled a wafer run using a 1.5 μ technology. A process was chosen that provided adequate density for the needed logic functions plus a high-voltage capability to allow stimulus pulses with up to 17 volts compliance.

Taking advantage of the wafer run, we have actually prepared our own MOSIS-like reticle with a number of different chips. Each wafer will have a repeating pattern of about 20 reticles. On each reticle will be 8 of the most recent design improved 2 MHz microstimulators (with all previously noted bugs fixed). Each of the 8 Microstimulators on the reticle has a different pre-programmed address, and laser cutting can be used to expand that address range if necessary. In addition, we have incorporated four 470 kHz suspended-carrier test Microstimulators on the reticle. These Suspended Carrier Microstimulators incorporate the rectification and data detection front developed at IIT with the control and output circuitry developed at AEMF. Also, other on-chip rectifi~~ca~~tier circuits developed by the Alfred E. Mann Foundation were tested on this run. Of the four SC μStims on each reticle, two are receive only and two have bi-directional communications.

The reticle also has a number of test circuits for individual functions. One test chip has a suspended-carrier front end separate from any stimulus circuitry. Another test chip includes a high-gain amplifier which will be investigated for use in sensor-mode μStims. Still another test chip contains individual field-effect and bipolar transistors which will be characterized to improve low-noise amplifier designs.

The wafer run has a total of 8 wafers. Depending on yield, this could provide up to 8x20x8, or 1240 improved microstimulators, plus a large quantity of suspended carrier microstimulators and other test chips. The present schedule calls for the first two wafers to be finished on November 19.* The remaining 6 wafers will be held at a processing step which will allow for changes to be made if problems are found in any of the circuits.

* At the time this report was being prepared for mailing (November 25) the wafers had just come in. The 2 MHz microstimulators were found to work perfectly. The occasional erratic behavior as noted in previous reports no longer appeared and the data detection was found to be very reliable, stable, and sensitive.